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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,376	07/29/2003	Michael P. Schrom	64862/PO66US/10502007	8953

37372 7590 06/07/2006

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EXAMINER

BOCKELMAN, MARK

ART UNIT	PAPER NUMBER
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3766

DATE MAILED: 06/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Applicant(s)	Applicant(s)	
	10/630,376	SCHROM ET AL.	
	Examiner	Art Unit	
	Mark W. Bockelman	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 41-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 41-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 41 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Winkler USPN 5,555,618 (alone) or alternatively, in view of Brown et al USPN 5,334,169.

Winkler teaches the apparatus substantially as claimed with respect to figures 10-12. Applicants may possibly differ in reciting that the “insulative material does not possess an inner layer boundary between the first and second radial depths”. Applicants are apparently referring to their disclosure in which two layers of insulation consisting of an outer insulation layer and an inner insulation layer (having the second

plurality of wires embedded therein) sandwich a the first plurality of wires, which in turn is covered by a heat shrink material and heated to fuse the layers together. It is noted that applicant's inner and outer insulation materials may be different materials. This would tend to still have somewhat of a boundary since the materials are merely melted together at the inner face. In this respect, if the claim language quoted above includes fused materials, it would appear that the embodiments of figures 10-12 are formed, the materials are in a molten state since they are shore D harness of 75 (column 10, lines 50-52), which requires heating for embedding the wires, see column 6 lines 18-23). Such heating would tend to fuse the two layers of polyurethane together. If not inherent, it would have been obvious to fuse these two layers of materials together as taught by Brown USPN 5,334,169. Brown teaches embedding wires of opposite winding in a tubular member (for carrying electricity - column 1 lines 24-25) wherein it is taught that the first and second layers are kept in a molten condition during extruding to produce a monolithic layer of material. Such is taught to be beneficial to prevent unwanted separation of the layers. To have produced the wire embedded lead of Winkler using the extruding techniques of Brown et al to prevent unwanted layer separation would have been obvious in view of Brown et al.

Claims 42-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winkler USPN 5,555,618 (alone) or alternatively, in view of Brown et al USPN 5,334,169. While Winkler teaches the outer covering of the medical lead of embodiments 10-12 have an outer diameter of .078 in (6 F), Winkler does not teach the the number of wires applicant states, but does teach any number (10 or more) may be

used. It is understood that as many could be used as desired and can be accommodated by altering the helical pitch of the wires along the lead shaft.

Claims 51 - 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winkler USPN 5,555,618 (alone or alternatively, in view of Brown et al USPN 5,334,169) and further in view of Starkebaum USPN 5733,322. While Winkler teaches his electrode lead maybe used in a variety of medical procedures he does not claim a pulse generator capable of applying stimulation energy to nerves. However, using leads with pulse generators that are capable of stimulating nerves would have been apparent to one of ordinary skill in the art. Starkebaum is cited as one of such pulse generators. As noted above applicant's sizes and number of conductors would have been obvious depending on the number of electrodes needed.

Response to Arguments

Applicant's arguments filed 3-13-2006 have been fully considered but they are not persuasive. Applicant's arguments are directed to allegations of differences between Winkler and applicant's specification. No factual showing of what constitutes an absence of a boundary layer is shown. The examiner maintains that some type of boundary layer is going to exist in the absence of such a showing because it is not seen how the extrusion process would allow some type of co-mingled materials. More importantly however is that the limitation that applicant wants to hinge patentability on seems to be on whether to heat the materials sufficiently to achieve co-mixing of the materials or not. The examiner does not consider the melting of the materials of Winkler

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to allow mixing to be a patentable step. It is prima facie obvious that more heating produces tighter bonding, a fairly obvious concept. Nevertheless the examiner has produced the Brown reference to show it was known to melt the layers to prevent the inadvertent peeling away of the outer layer during torquing, with which both of the references are concerned. The applicant characterizes the Brown reference as non-analogous art despite it too be is a catheter with wires embedded therein between layers and is concerned with torquing. The examiner wholly disagrees with such a characterization. Both devices are produced in a similar manner and are used for accessing body lumens. Notwithstanding, the examiner considers the melting of materials to form a stronger bond to have been prima facie obvious to one of skill in the art.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark W. Bockelman whose telephone number is (571) 272-4941. The examiner can normally be reached on Monday - Friday 10:00 to 6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571) 272 -6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MWB

May 30, 2006

